

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PUREWICK CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. _____
)	
SAGE PRODUCTS, LLC,)	JURY TRIAL DEMANDED
)	
Defendant.)	

COMPLAINT

Plaintiff PureWick Corporation (“PureWick” or “Plaintiff”), hereby demands a jury trial and alleges the following against Defendant Sage Products, LLC (“Sage” or “Defendant”):

NATURE OF ACTION

1. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. §§ 1, *et seq.*
2. Plaintiff has filed this lawsuit to stop Defendant’s unlawful infringement of Plaintiff’s patented inventions and to obtain damages, an injunction, and other relief.

THE PARTIES

3. PureWick Corporation is a corporation organized and existing under the laws of the State of California with a place of business located at 2030 Gillespie Way, Suite 109, El Cajon, CA 92020. PureWick is a wholly owned subsidiary of C.R. Bard, Inc.
4. On information and belief, Sage is incorporated under the laws of Delaware, and has a place of business at 3909 Three Oaks Road, Cary, IL 60013.

JURISDICTION AND VENUE

5. This is an action for patent infringement arising under the patent laws of the United States of America, 35 U.S.C. §1, et. seq., including 35 U.S.C. § 271. This Court has exclusive subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Sage based at least on Sage's incorporation in the State of Delaware.

7. Venue is proper in this Court under 28 U.S.C. § 1400(b) because Sage is incorporated in, and therefore resides in, the State of Delaware.

FACTUAL BACKGROUND

PureWick™ FEC Solution

8. PureWick developed and patented a groundbreaking female external catheter, the PureWick™ FEC Solution. PureWick's female external catheter provides an incontinence solution for women, designed to reduce catheter-associated urinary tract infections ("CAUTI") and skin damage caused by urine-soaked diapers and bedding. The PureWick™ FEC Solution has shown an ability to consistently capture and take away urine, while improving users' sleep quality as they do not have to be awakened for diaper changes.

The Patents-in-Suit

9. On March 12, 2019 United States Patent and Trademark Office ("the USPTO") duly and legally issued U.S. Patent No. 10,226,376 ("the '376 patent"), titled "Apparatus And Methods For Receiving Discharged Urine." PureWick is the owner by assignment of the '376 patent. A true and accurate copy of the '376 patent is attached hereto as Exhibit 1.

10. On August 27, 2019, the USPTO duly and legally issued U.S. Patent No. 10,390,989 ("the '989 patent"), titled "Apparatus And Methods For Receiving Discharged

Urine.” PureWick is the owner by assignment of the '989 patent. A true and accurate copy of the '989 patent is attached hereto as Exhibit 2.

Defendant's Accused Product

11. In or around October 2017, Sage introduced a competing product to the PureWick™ FEC called the PrimaFit™, which is identified at <https://sageproducts.com/primafit-external-urine-management-system-for-females/>.

12. On information and belief, in 2021 Sage began making, offering for sale, and selling a new version of the PrimaFit (“PrimaFit 2.0”). A brochure marketing the PrimaFit 2.0 (attached as Exhibit 3) is available at <https://www.stryker.com/content/dam/stryker/sage/products/primafit/resources/Sage-PrimaFit-Brochure.pdf> and is shown below.



13. On information and belief, Sage makes, uses, offers to sell, and/or sells the PrimaFit 2.0 in the United States, and/or imports the PrimaFit 2.0 into United States.

COUNT I

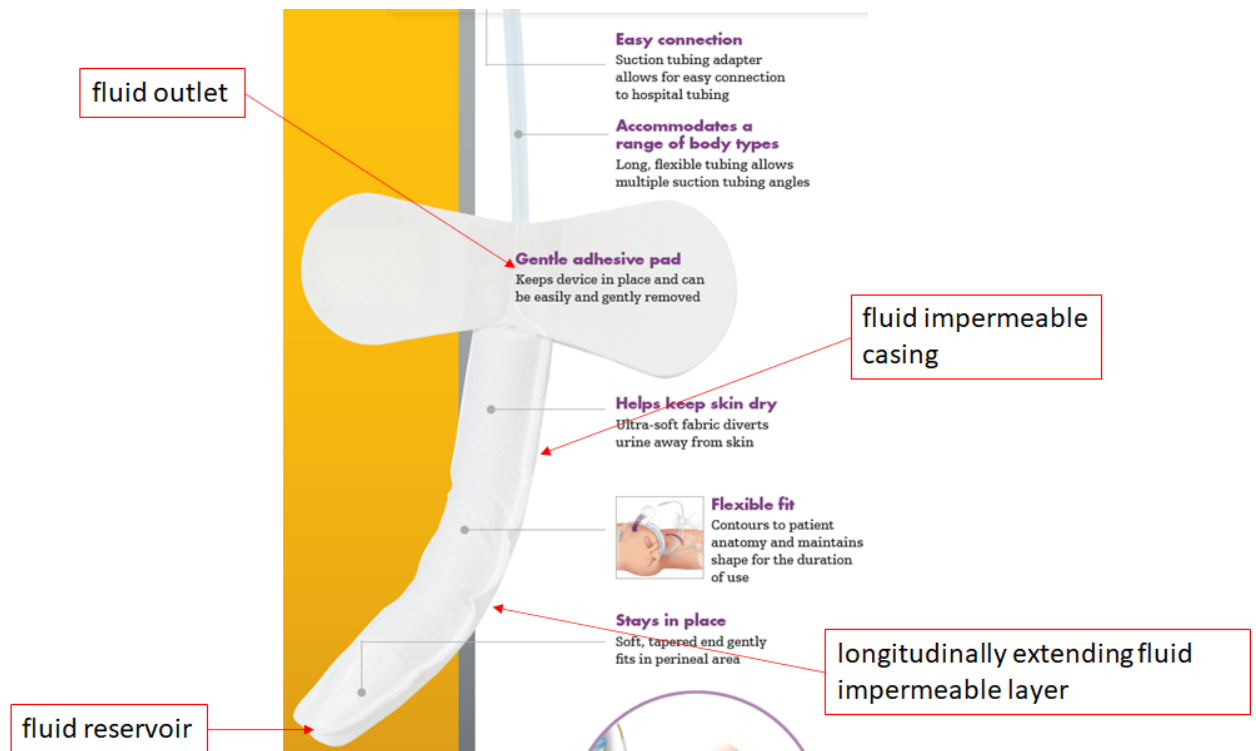
INFRINGEMENT OF THE '376 PATENT

14. The allegations of the preceding paragraphs are incorporated by reference as if fully set forth herein.

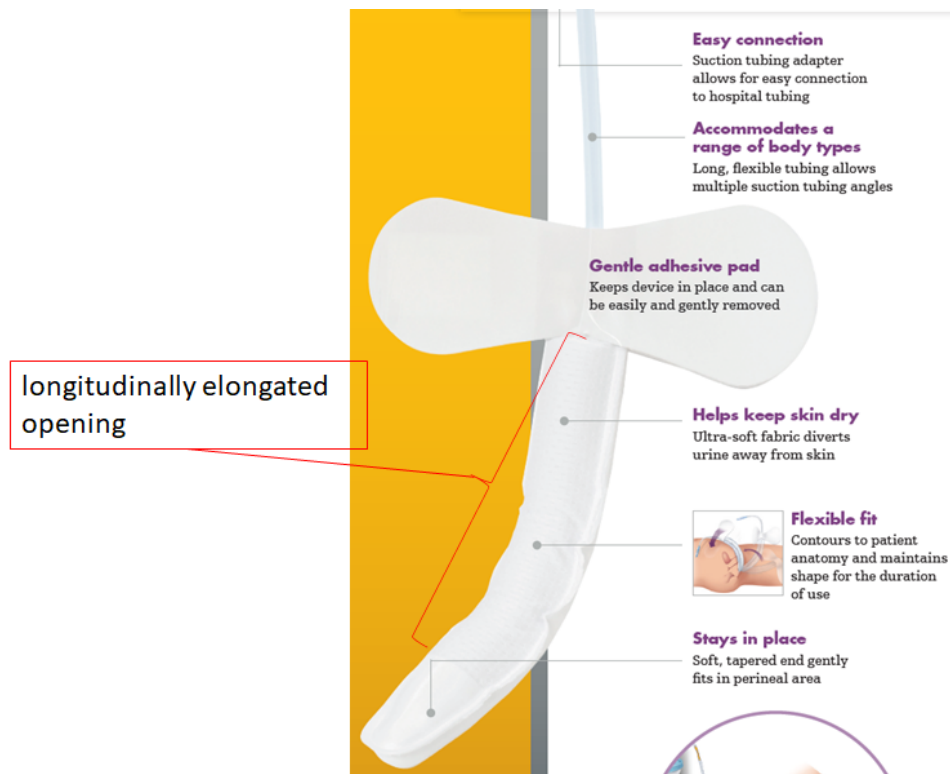
15. Defendant has directly infringed, and continues to directly infringe claim 1 of the '376 patent by making, using, offering for sale, selling, and/or importing into the United States the PrimaFit 2.0 product, and contributed to and/or induced infringement of the '376 patent by others, including hospitals, patients, and other customers.

16. For example, and without limitation, the PrimaFit 2.0 product meets every limitation of at least independent claim 1 of the '376 patent, and Defendant's making, using, offering for sale, selling, and/or importing the PrimaFit 2.0 product into the United States directly infringes at least claim 1 of the '376 patent under 35 U.S.C. § 271(a).

17. The PrimaFit 2.0 product is "[a]n apparatus comprising: a fluid impermeable casing having a fluid reservoir at a first end, a fluid outlet at a second end, and a longitudinally extending fluid impermeable layer coupled to the fluid reservoir and the fluid outlet." Exhibit 1 at 36:9-13. For example:

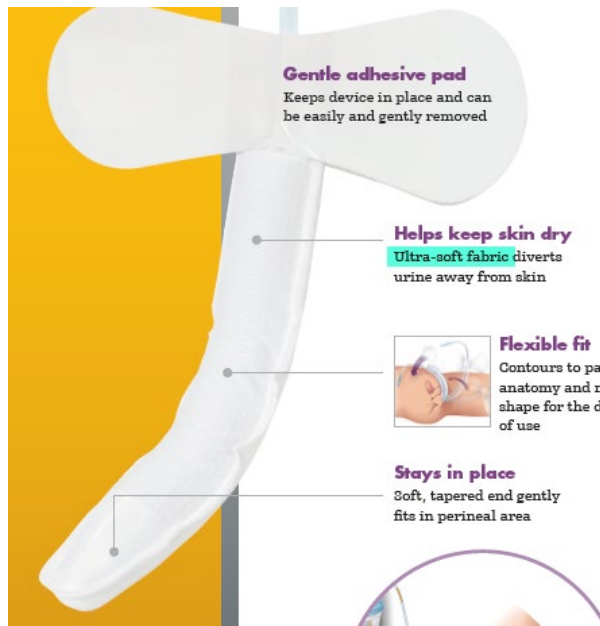


18. The “longitudinally extending fluid impermeable layer” of the PrimaFit 2.0 product “defin[es] a longitudinally elongated opening between the fluid reservoir and the fluid outlet.” Exhibit 1 at 36:13-15. For example:

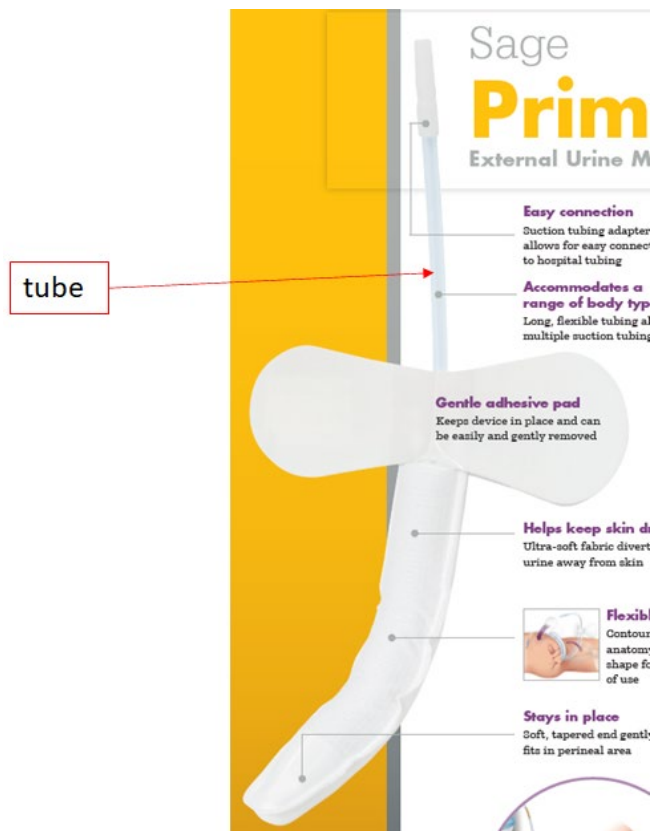


19. The PrimaFit 2.0 product includes “a fluid permeable support disposed within the casing with a portion extending across the elongated opening, wherein the fluid permeable support is distinct from and at least proximate to the fluid reservoir.” Exhibit 1 at 36:16-19. The PrimaFit 2.0 includes a permeable foam support disposed within the casing with a portion extending across the elongated opening. The foam support is distinct from and proximate to the fluid reservoir.

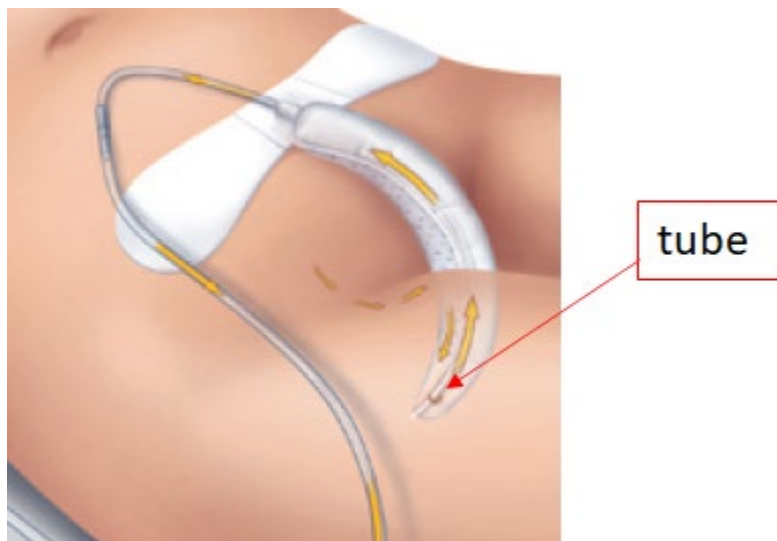
20. The PrimaFit 2.0 product includes “a fluid permeable membrane disposed on the support and covering at least the portion of the support that extends across the elongated opening, so that the membrane is supported on the support and disposed across the elongated opening.” Exhibit 1 at 36:20-24. In particular, the “ultra-soft fabric” shown in the image below is a fluid permeable membrane.



21. The PrimaFit 2.0 product includes “a tube having a first end disposed in the reservoir and extending behind at least the portion of the support and the portion of the membrane disposed across the elongated opening and extending through the fluid outlet to a second, fluid discharge end.” Exhibit 1 at 36:25-29. For example, the image below shows a tube extending from the PrimaFit 2.0.



22. The brochure also shows that the tube extends from the reservoir through the device, behind at least the portion of the support and the portion of the membrane disposed across the elongated opening, and out of the fluid outlet.



23. The PrimaFit 2.0 product is an apparatus “configured to be disposed with the opening adjacent to a urethral opening of a user, to receive urine discharged from the urethral opening through the opening of the fluid impermeable layer, the membrane, the support, and into the reservoir, and to have the received urine withdrawn from the reservoir via the tube and out of the fluid discharge end of the tube.” Exhibit 1 at 36:30-36. For example:

Step 6 Position device vertically with tapered end facing downward and fabric facing patient’s labia.

Step 7 Align tapered end with perineum and place device between the labia and against the urethral opening. Ensure fabric is covering the urethral meatus.

Step 8 Curve the device toward the patient’s lower abdomen.

Exhibit 4. The PrimaFit 2.0 product brochure explains the product is configured to “divert[] urine away from the patient’s skin. Urine is then absorbed into the system’s core and suctioned into a collection canister.” Exhibit 3. The brochure also depicts urine being withdrawn from the reservoir via the tube and out of the fluid discharge end of the tube:



24. Thus, the PrimaFit 2.0 product meets every limitation of at least independent claim 1 of the '376 patent and Defendant directly infringe claim 1 in violation of 35 U.S.C. §

271(a) by making, using, offering for sale, selling, and/or importing the PrimaFit 2.0 product into the United States.

25. Defendant also has indirectly infringed and continues to indirectly infringe the claims of the '376 patent by inducing infringement pursuant to 35 U.S.C. § 271(b) and/or contributing to infringement pursuant to 35 U.S.C. § 271(c).

26. On information and belief, in violation of 35 U.S.C. § 271(b), Defendant specifically intended to induce infringement of the '376 patent by its customers and users of the PrimaFit 2.0 product and had knowledge that the inducing acts would cause infringement or was willfully blind to the possibility that their inducing acts would cause infringement.

27. Defendant knew or should have known of the '376 patent as early as March 12, 2019 when the patent issued, and no later than August 12, 2019 when PureWick asserted the '376 patent against Sage in *PureWick Corp. v. Sage Products, LLC*, C.A. No. 19-cv-01508-MN.

28. On information and belief, Defendant's customers directly infringe the '376 patent. For example, when the PrimaFit 2.0 product is sold to hospitals, medical professionals, and patients, those customers infringe at least independent claim 1 of the '376 patent through the use of the PrimaFit 2.0 product.

29. On information and belief, Defendant specifically intends for customers to infringe the '376 patent. Defendant encourages infringement by customers at least by providing product support that instructs users on how to use the PrimaFit 2.0 product.

30. On information and belief, despite Defendant's knowledge of the '376 patent and knowledge that customers will necessarily infringe the '376 patent when the PrimaFit 2.0 product is used as instructed, Defendant continues to encourage infringement.

31. Defendant also contributes to infringement of the '376 patent by Defendant's customers in violation of 35 U.S.C. §271(c). On information and belief, Defendant was aware of the '376 patent at least as early as March 2019 and no later than August 12, 2019. On information and belief, Defendant offers to sell and sells within the United States the PrimaFit 2.0 product knowing that it constitutes a material part of the claimed inventions, knowing that the PrimaFit 2.0 product is especially made or especially adapted for use in infringing the '376 patent, and knowing that the PrimaFit 2.0 product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

32. Defendant has committed and continues to commit all of the above acts of infringement without license or authorization.

33. Sage has had actual notice of its infringement of the '376 patent based on positions taken by PureWick in *PureWick Corp. v. Sage Products, LLC*, C.A. No. 19-1508-MN.

34. As a result of Defendant's infringement of the '376 patent, Plaintiff has suffered damages and will continue to suffer damages.

35. On information and belief, the infringement of the '376 patent by Defendant has been and continues to be willful. Defendant has had knowledge of the '376 patent and knowledge that the PureWick™ FEC Solution is covered by the '376 patent since at least as early as August 12, 2019. On information and belief, Defendant copied the PureWick™ FEC Solution despite knowing that the PureWick™ FEC Solution is covered by the '376 patent. On information and belief, Defendant subsequently developed, offered for sale and sold the PrimaFit 2.0 with knowledge of the '376 patent and with knowledge that the PrimaFit 2.0 infringes the '376 patent. Defendant has thus sold the PrimaFit 2.0 knowing of the risk of infringement and/or in view of a risk of infringement that was sufficiently obvious that it should have been known to

Defendant. Despite this risk, Defendant has deliberately continued to infringe in a wanton, malicious, and egregious manner, with reckless disregard for PureWick's patent rights. Thus, Defendant's infringing actions have been and continue to be consciously wrongful, entitling PureWick to increased damages under 35 U.S.C. § 284.

36. Under 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement. Defendant's wrongful conduct has caused and will continue to cause Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent right to exclude others from making, using selling, offering to sell, and/or importing Plaintiff's patented inventions. On information and belief, Defendant will continue to infringe the '376 patent unless permanently enjoined by the Court.

COUNT II

INFRINGEMENT OF THE '989 PATENT

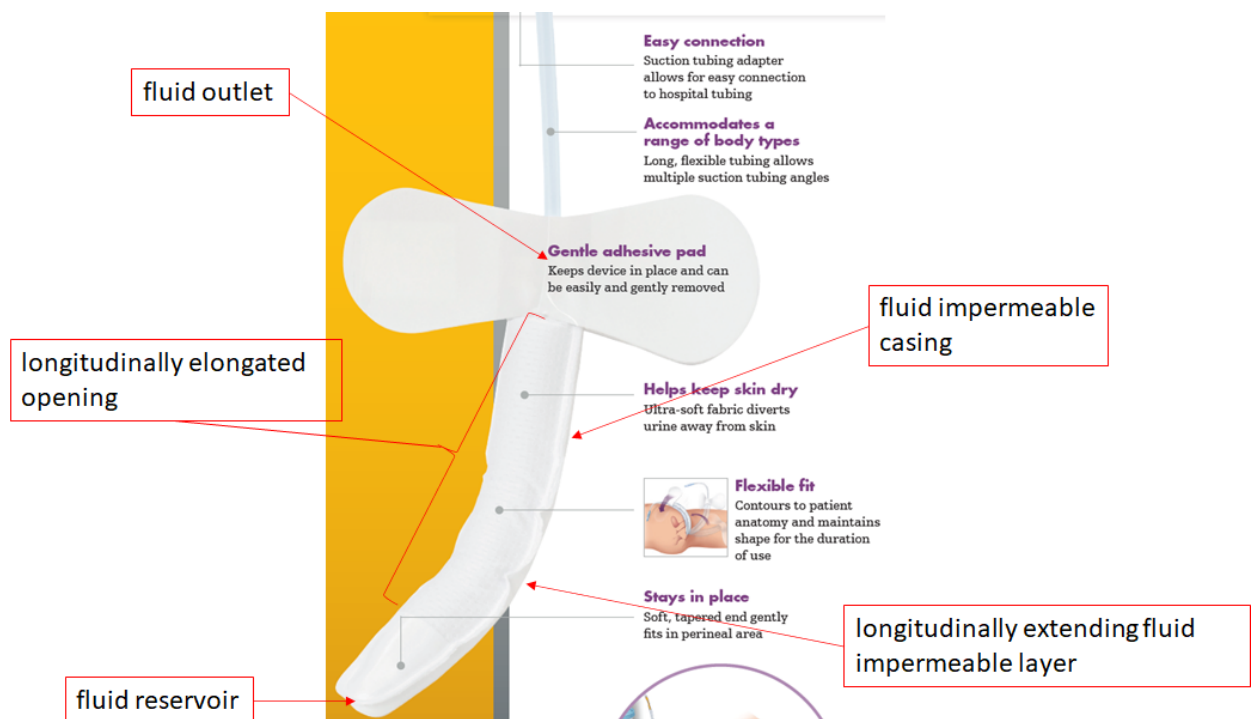
37. The allegations in the preceding paragraphs are incorporated by reference as if fully set forth herein.

38. Defendant has directly infringed, and continues to directly infringe claim 1 of the '989 patent by making, using, offering for sale, selling, and/or importing into the United States the PrimaFit 2.0 product, and contributed to and/or induced infringement of the '989 patent by others, including hospitals, patients, and other customers.

39. For example, and without limitation, on information and belief, the PrimaFit 2.0 product meets every limitation of at least independent method claim 1 of the '989 patent, and Defendant's making, using, offering for sale, selling, and/or importing the PrimaFit 2.0 product into the United States directly infringes at least claim 1 of the '989 patent under 35 U.S.C. § 271(a).

40. The use of the PrimaFit 2.0 product practices a “method comprising: disposing in operative relationship with the urethral opening of a female user a urine collecting apparatus.” Exhibit 2 at 27:44-47. Defendant’s Instructions for Use manual instructs the user to “[a]lign tapered end with perineum and place device between the labia and against the urethral opening. Ensure fabric is covering the urethral meatus” and illustrates such positioning on the user. Exhibit 4.

41. As shown in the photographs below, the PrimaFit 2.0 product includes “a fluid impermeable casing having a fluid reservoir at a first end, a fluid outlet at a second end, and a longitudinally extending fluid impermeable layer coupled to the fluid reservoir and the fluid outlet and defining a longitudinally elongated opening between the fluid reservoir and the fluid outlet.” Exhibit 2 at 27:48-53.



42. The PrimaFit 2.0 product includes “a fluid permeable support disposed within the fluid impermeable casing with a portion extending across the longitudinally elongated opening,

wherein the fluid permeable support is distinct from and at least proximate to the fluid reservoir.”

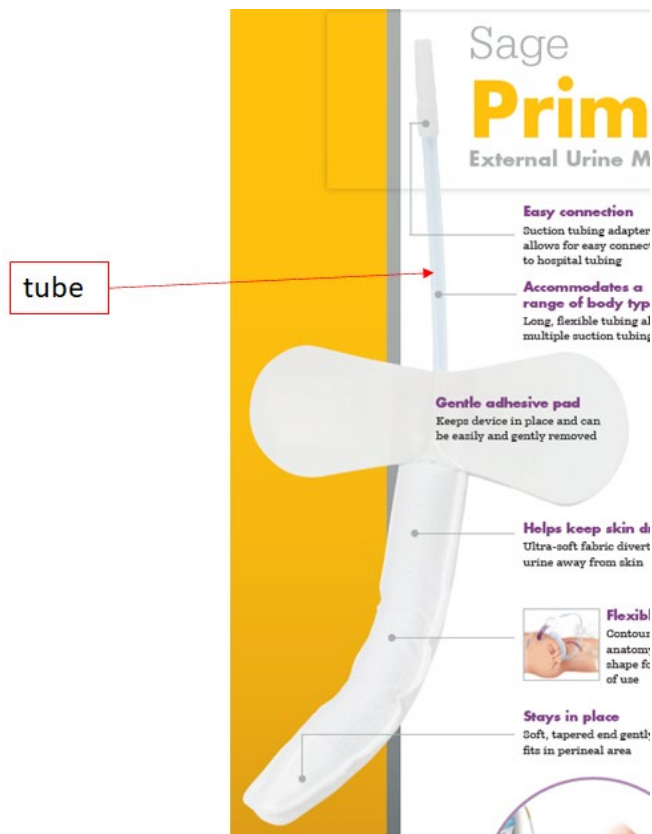
Exhibit 2 at 54-58. The PrimaFit 2.0 includes a permeable foam support disposed within the casing with a portion extending across the elongated opening. The foam support is distinct from and proximate to the fluid reservoir.

43. The PrimaFit 2.0 product includes “a fluid permeable membrane disposed on the fluid permeable support and covering at least the portion of the fluid permeable support that extends across the longitudinally elongated opening, so that the fluid permeable membrane is supported on the fluid permeable support and disposed across the longitudinally elongated opening.” Exhibit 2 at 27:59-65. In particular, the “ultra-soft fabric” is a fluid permeable membrane.

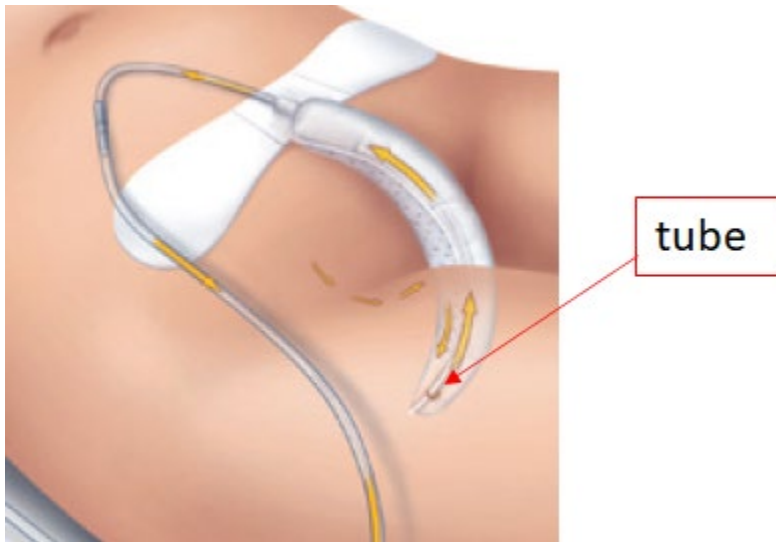


44. The PrimaFit 2.0 product includes “a tube having a first end disposed in the fluid reservoir and extending behind at least the portion of the fluid permeable support and the portion of the fluid permeable membrane disposed across the longitudinally elongated opening and extending through the fluid outlet to a second, fluid discharge end, the operative relationship

includes the longitudinally elongated opening being adjacent to the urethral opening.” Exhibit 2 at 27:66-28:4. For example, the image below shows a tube extending from the PrimaFit 2.0.



45. The brochure also shows that the tube extends from the reservoir through the device, behind at least the portion of the support and the portion of the membrane disposed across the elongated opening, and out of the fluid outlet.



Use of the PrimaFit 2.0 product “allow[s] urine discharged from the urethral opening to be received through the longitudinally elongated opening of the longitudinally extending fluid impermeable layer, the fluid permeable membrane, the fluid permeable support, and into the fluid reservoir” and “allow[s] the received urine to be withdrawn from the fluid reservoir via the tube and out of the fluid discharge end of the tube.” Exhibit 2 at 28:5-15. Defendant’s Product Brochure explains “[w]hen properly positioned, PrimaFit’s ultra-soft fabric diverts urine away from the patient’s skin. Urine is then absorbed into the system’s core and suctioned into a collection canister, helping keep the skin dry and addressing a risk factor of incontinence-associated dermatitis (IAD).” Exhibit 3. The brochure also depicts urine being withdrawn from the reservoir via the tube and out of the fluid discharge end of the tube:



46. Thus, the use of the PrimaFit 2.0 product meets every limitation of at least independent claim 1 of the '989 patent and Defendant directly infringes claim 1 in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, selling, and/or importing the PrimaFit 2.0 product into the United States.

47. Defendant also has indirectly infringed and continues to indirectly infringe the claims of the '989 patent by inducing infringement pursuant to 35 U.S.C. § 271(b) and/or contributing to infringement pursuant to 35 U.S.C. § 271(c).

48. On information and belief, in violation of 35 U.S.C. § 271(b), Defendant specifically intended to induce infringement of the '989 patent by its customers and users of the PrimaFit 2.0 product and had knowledge that the inducing acts would cause infringement or was willfully blind to the possibility that their inducing acts would cause infringement.

49. Defendant knew or should have known of the '989 patent as early as August 27, 2019 when the patent issued, and no later than October 2, 2019 when PureWick asserted the '376 patent against Sage in *PureWick Corp. v. Sage Products, LLC*, C.A. No. 19-cv-01508-MN.

50. On information and belief, Defendant's customers directly infringe the '989 patent. For example, when the PrimaFit 2.0 product is sold to hospitals, medical professionals,

and patients, those customers infringe at least independent claim 1 of the '989 patent through the use of the PrimaFit 2.0 product.

51. On information and belief, Defendant specifically intends for customers to infringe the '989 patent. Defendant encourages infringement by customers at least by providing product support that instructs users on how to use the PrimaFit 2.0 product.

52. On information and belief, despite Defendant's knowledge of the '989 patent and knowledge that customers will necessarily infringe the '989 patent when the PrimaFit 2.0 product is used as instructed, Defendant continues to encourage infringement.

53. Defendant also contributes to infringement of the '989 patent by Defendant's customers in violation of 35 U.S.C. §271(c). On information and belief, Defendant was aware of the '989 patent at least as early as August 2019 and no later than October 2, 2019. On information and belief, Defendant offers to sell and sells within the United States the PrimaFit 2.0 product knowing that it constitutes a material part of the claimed inventions, knowing that the PrimaFit 2.0 product is especially made or especially adapted for use in infringing the '989 patent, and knowing that the PrimaFit 2.0 product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

54. Defendant has committed and continues to commit all of the above acts of infringement without license or authorization.

55. Sage has had actual notice of its infringement of the '989 patent based on positions taken by PureWick in *PureWick Corp. v. Sage Products, LLC*, C.A. No. 19-1508-MN.

56. As a result of Defendant's infringement of the '989 patent, Plaintiff has suffered damages and will continue to suffer damages.

57. On information and belief, the infringement of the '989 patent by Defendant has been and continues to be willful. Defendant has had knowledge of the '989 patent and knowledge that use of the PureWick™ FEC Solution is covered by the '989 patent since at least as early as October 2, 2019. On information and belief, Defendant copied the PureWick™ FEC Solution despite knowing that the PureWick™ FEC Solution is covered by the '989 patent. On information and belief, Defendant subsequently developed, offered for sale and sold the PrimaFit 2.0 with knowledge of the '989 patent and with knowledge that the use of the PrimaFit 2.0 infringes the '989 patent. Defendant has thus sold the PrimaFit 2.0 product knowing of the risk of infringement and/or in view of a risk of infringement that was sufficiently obvious that it should have been known to Defendant. Despite this risk, Defendant has deliberately continued to infringe in a wanton, malicious, and egregious manner, with reckless disregard for PureWick's patent rights. Thus, Defendant's infringing actions have been and continue to be consciously wrongful, entitling PureWick to increased damages under 35 U.S.C. § 284.

58. Under 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement. Defendant's wrongful conduct has caused and will continue to cause Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent right to exclude others from making, using selling, offering to sell, and/or importing Plaintiff's patented inventions. On information and belief, Defendant will continue to infringe the '989 patent unless permanently enjoined by the Court.

JURY DEMAND

59. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff respectfully demands a trial by jury of all issues so triable.

PRAYERS FOR RELIEF

WHEREFORE, Plaintiff requests that judgment be entered in favor of Plaintiff and against Defendant as follows:

- a. A judgment that the '376 and '989 patents are directly and indirectly infringed by Defendant;
- b. An order permanently enjoining Defendant, its affiliates and subsidiaries, and each of its officers, agents, servants, and employees and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing products claimed in any of the claims of the '376 and '989 patents, and from causing or encouraging others to use, sell, offer for sale, or import products that infringe any claim of the '376 and '989 patents, until after the expiration dates of the '376 and '989 patents, including any extensions and/or additional periods of exclusivity to which Plaintiff is or may become entitled;
- c. An order awarding damages under 35 U.S.C. § 284 in an amount sufficient to compensate Plaintiff for its damages arising from infringement by Defendant, including, but not limited to, lost profits and/or a reasonable royalty, together with pre-judgment and post-judgment interest, and costs;
- d. An order awarding treble damages for willful infringement by Defendant, pursuant to 35 U.S.C. § 284;
- e. An accounting and/or supplemental damages for all damages occurring after any discovery cutoff and through the Court's decision regarding the imposition of a permanent injunction;
- f. A judgment declaring that this case is exceptional and awarding Plaintiff its reasonable costs and attorneys' fees pursuant to 35 U.S.C. § 285; and

- g. Such other relief as this Court or a jury may deem proper and just under the circumstances.

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